

6-2-14

Trenbolone was one of several chemicals tested at ORD, NHEERL, MED as a positive control representative of an endocrine mode of action used as part of the EDSP Tier 2 Test protocol development for the Endocrine Disrupter Screening Program run by the Office of Science Coordination and Policy (OSCP) of OCSPP. MED developed an amphibian EDSP Tier 2 test protocol, the Larval Amphibian Growth and Development Assay (LAGDA), and an EDSP Tier 2 fish test protocol, the Medaka Multi-generation Test (MMT). The test protocols were reviewed as part of an OSCP Science Advisory Panel (SAP) review of Proposed EDSP Tier 2 Ecotoxicity Tests held June 25-28, 2013. As part of the FACA review, the trenbolone data and summary of the findings is publically available on the OCSPP/OSCP Science Advisory Panel meetings public docket.

Below are the docket link and a listing of docket files pertaining to the MED work only. OSCP should be contacted for additional trenbolone data included in ISRs for other ecological species, e.g., Japanese quail.

#### **SAP docket link**

The Integrated Summary Reports (ISR) for both fish (MMT) and frog (LAGDA) can be found by going to EPA Science Advisory Panel website, under June 25-28, 2013 meeting on Proposed EDSP Tier 2 Ecotoxicity Tests, and looking under Meeting Materials: [filed under docket ID: EPA-HQ-OPP-2013-0182] The EPA site will have a link to the Regulations.gov site where the pdfs are downloadable.

<http://www.epa.gov/scipoly/sap/meetings/2013/062513meeting.html#materials>

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#### **LAGDA**

##### **Validation of the Larval Amphibian Growth and Development Assay (LAGDA): Integrated Summary Report (ISR)**

EPA-HQ-OPP-2013-0182-0006.pdf

##### **ERRATA on Statistical Analysis**

Attachment (1) to FIFRA SAP ERRATA Memo on Statistical Analysis (FIFRA SAP ERRATA EPA-HQ-OPP-2013-0182-0071.pdf )

##### **LAGDA Errata Validation of the Larval Amphibian Growth and Development Assay: Integrated Summary Report**

LAGDA\_Errata\_Validation\_of\_the\_Larval\_Amphibian\_Growth\_and\_Development\_Assay\_Integrated\_Summary\_Report.pdf

##### **Other ORD, NHEERL, MED Cited in LAGDA ISR:**

Olmstead AW, Kosian PA, Johnson R, Blackshear PE, Haselman J, Blanksma C, Korte JJ, Holcombe GW, Burgess E, Lindberg-Livingston A, Bennett BA, Woodis KK, Degitz SJ. 2012. Trenbolone causes mortality and altered sexual differentiation in *Xenopus tropicalis* during larval development. Environmental Toxicology and Chemistry 31(10):2391-2398.

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**MMT**

**Validation of the Medaka Multigeneration Test (MMT): Integrated Summary Report (ISR):**

EPA-HQ-OPP-2013-0182-0005.pdf

**ERRATA on Statistical Analysis**

Attachment (2) to FIFRA SAP ERRATA Memo on Statistical Analysis (FIFRA SAP ERRATA EPA-HQ-OPP-2013-0182-0071.pdf)

**Errata MMT (2) Validation of the Medaka Multigeneration Test: Integrated Summary Report**

Errata\_MMT\_(2)\_Validation\_of\_the\_Medaka\_Multigeneration\_Test\_Integrated\_Summary\_Report.pdf

Additional ISR Appendices mentioning Trenbolone data:

**Appendix F: Pathology Guidance**

EPA-HQ-OPP-2013-0182-0031.pdf

**Appendix G: Statistical Procedures**

EPA-HQ-OPP-2013-0182-0032.pdf

**Appendix H: Test data, graphs, etc**

EPA-HQ-OPP-2013-0182-0033.pdf

**Appendix I: Power Analysis**

EPA-HQ-OPP-2013-0182-0034.pdf